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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,526	10/11/2005	Toshikazu Kamiya	00005.001278.	4344

5514 7590 05/20/2010

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EXAMINER	
MCCORMICK, MELENIE LEE	
ART UNIT	PAPER NUMBER
1655	
MAIL DATE	DELIVERY MODE
05/20/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,526	KAMIYA ET AL.	
	Examiner	Art Unit	
	MELENIE MCCORMICK	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6,7,9,18 and 20* is/are pending in the application.

4a) Of the above claim(s) *3,18 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 6-7, 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' remarks with claim amendments received 12 February 2010 have been received and considered.

Claims 1, 3, 6-7, 9, 18 and 20 are pending.

Claims 3, 18 and 20 stand withdrawn from consideration as being drawn to the non-elected invention.

Claims 1, 6-7, and 9 are presented for examination on the merits.

Maintained Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6-7, and 9 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sorgente et al. (US 6,162,787) in view of Guardia et al. (2001) in view of Balado (1953) and further in view of Matsuda et al. (1999) for the reasons set forth in the previous Office Action, which are restated below.

Sorgente et al. beneficially teach that oral administration of a composition comprising glucosamine or its salts and chondroitin sulfate and/or its salts is effective for treating arthritis (see e.g. claims 1 and 29). Sorgente et al. further teaches that the arthritis may be osteoarthritis or rheumatoid arthritis (see e.g. claims 21-22). Sorgente et al. also teaches that the composition may contain auxiliary compounds, such as binders, vitamins, amino acids, fillers, gelatin, etc (see e.g. col 5, lines 51-57). Sorgente also discloses that the composition may be formulated as a tablet, capsule, suspension, aerosol spray and the like. A powder could be added to a food (i.e. a food additive) and a suspension reads on a drink.

Sorgente et al. does not explicitly teach that the composition additionally contains Hydrangea macrophylla or an extract thereof.

Guardia et al. beneficially teach that in an experimental model for inflammation, which is a suitable and simple model for evaluating potential anti-arthritic agents was used to determine the anti-inflammatory activity of flavonoids in adjuvant arthritis (see e.g. page 685-Discussion). Guardia et al. further teach that rutin was extremely effective in reducing inflammation (see e.g. page 685-Discussion). Guardia et al. further teach that the role of dietary flavonoids in the treatment of inflammatory diseases, such as rheumatoid arthritis is promising (see e.g. page 687).

Balado beneficially teaches that rutin was extracted and identified from the blossoms of *Hydrangea macrophylla* (see e.g. abstract).

Matsuda et al. beneficially teach that chemical constituents with anti-histamine activity were extracted from the leaves of *Hydrangea macrophylla* Seringe var. thunbergii Makino (see e.g. abstract).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a composition for use in treating arthritis comprising an extract of *Hydrangea macrophylla*, glucosamine and chondroitin sulfate. A person of ordinary skill in the art would have had a reasonable expectation of success in doing so based upon teaching of Sorgente et al. that a composition comprising glucosamine or its salts and chondroitin sulfate and/or its salts is effective for treating arthritis (see e.g. claims 1 and 29). In addition, based upon the teaching of Balado that rutin is extracted from *Hydrangea macrophylla* and the teaching of Guardia et al. that rutin is extremely effective in reducing inflammation in a rat arthritis model and shows promise for treating arthritis, a person of ordinary skill in the art would have been motivated to extract *Hydrangea macrophylla* for the rutin contained therein and add this extract to other known anti-arthritic agents, such as glucosamine and chondroitin sulfate as taught by Sorgente et al. "The idea for combining them flows logically from their having been used individually in the prior art"; *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.). This rejection is based upon the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the

ingredients, See *In re Sussman*, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943). A person of ordinary skill in the art would have had a reasonable expectation of success in particularly using the variety *Hydrangea macrophylla* Seringe var. thunbergii Makino because this was a known variety at the time and was known to contain therapeutic chemical constituents. Therefore, since *Hydrangea macrophylla* Seringe var. thunbergii Makino is simply a variety of *Hydrangea macrophylla,* one of ordinary skill in the art would reasonably expect this variety, which is known to chemical constituents in the leaves, to contain rutin in the flowers, as disclosed by Balado. A person of ordinary skill in the art would have a reasonable expectation of success in optionally choosing a particular part of the plant for extraction, such as the leaves, since the leaves are known to contain useful chemical constituents. As previously stated, Sorgente et al. also disclose that the composition may be formulated as a tablet, capsule, suspension, aerosol spray and the like. A powder could be added to a food (i.e. a food additive) and a suspension reads on a drink. It would have therefore been obvious to one of ordinary skill in the art to formulate a composition comprising glucosamine, chondroitin sulfate and an extract *Hydrangea macrophylla* Seringe var. thunbergii Makino in these forms. A person of ordinary skill in the art would have also had a reasonable expectation of success in providing the active ingredients in the composition (the glucosamine or chondroitin sulfate and rutin) within a ratio of 1:10 to 10:1 parts by weight. Please note that this range encompasses a vast number of possible parts by weight of each component and encompasses adding the components in equal amounts. It would have been obvious to one of ordinary skill in the art to at least try adding the components of a

composition rendered obvious by the instantly cited references in equal amounts and to adjust the amounts from there in order to optimize the composition for effectiveness.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicants argue that the claims have been narrowed and are now allowable. While the instant claims have been narrowed to the particular glycosaminoglycan chondroitin sulfate, as discussed above, a composition comprising chondroitin sulfate in combination with an extract of leaves or branch ends of *Hydrangea macrophylla* Seringe var. thunbergii Makino and glucosamine was obvious at the time of the instantly claimed invention. In addition, while the claims have been narrowed from parts (i) and (ii) being present in an amount of 1:50 to 50:1 parts by weight to 1:10 to 10:1 parts by weight, the claims are still not commensurate in scope with the synergistic result disclosed in the instant specification (pages 38-40) and the Kamiya's declaration submitted 8/14/2009. The declaration points to a synergistic effect demonstrated in example 3 at pages 38-40 of the specification. The composition of group 4 in Example 3 comprises 0.25% Amacha (hydrangea leaf) extract, 0.5% glucosamine and 0.5% Chondroitin sulfate. This composition, comprising these particular amounts of each

component, has an unexpected result, since half of the amount of each component is used in the composition as compared to the amount of each component used individually to suppressed an increase in arthritis scores. The instant claims, however, are not drawn to a composition which comprises these components in these amounts (0.25% Amacha (hydrangea leaf) extract, 0.5% glucosamine and 0.5% Chondroitin sulfate). Instead, the composition of the instant claims is draw to a composition comprising leaves or branch ends of Hydrangea macrophylla Seringe var Thunbergii Makino (amacha) or an extract of said branch ends or leaves (i) and glucosamine or salt thereof and chondroitin sulfate or a salt thereof (ii) wherein (i) and (ii) are present in a ration of 1:10 to 10:1 parts by weight (see e.g. claim 1). The amount of 1:10 to 10:1 is very broad and includes a 1:1 ratio, which, as discussed above, is obvious. The declaration points to example 3, which provides a synergistic effect for 0.25% Amacha extract, 0.5% glucosamine and 0.5% Chondroitin sulfate in a composition. This narrow disclosure does not provide support for the broad range instantly claimed. Given that the results of example 3 are unexpected, which is supported by the declaration, (see page 9 of the declaration), one of ordinary skill in the art would not expect that all amounts encompassed by the broad range of 1:10 to 10:1 would result in synergism. Therefore, the claims are not commensurate in scope with the unexpected result and there is lack of evidence to support an unexpected result using amounts of each component which fall within the broad range instantly claimed.

The rejection is therefore deemed proper and is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELENIE MCCORMICK whose telephone number is (571)272-8037. The examiner can normally be reached on M-F 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melenie McCormick

/Patricia Leith/
Primary Examiner, Art Unit 1655
for MM